

Exploring the world of ambulatory surgery[☆]

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Abstract

The 5th James H. Nicoll Memorial lecture was delivered at the 5th International Congress on Ambulatory Surgery, Boston, Massachusetts, 2003. A summary of historic events and modern concepts of care for the ambulatory surgical patient is summarized. Current guidelines of the American Society of Anesthesiologists were developed using an evidence-based model. Data, however, are lacking and conclusions based largely on consensus of experts. Morbidity and mortality are low frequency events. Large populations must be studied to identify and correct causative factors. Data from recent studies are noted and critiqued. Office-based surgery is a specific venue of concern.

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I am honored to have been invited to deliver the 5th James H. Nicoll Memorial lecture. It is especially gratifying for me to be able to address the 5th International Congress on Ambulatory Surgery at which so many of my friends and professional associates are in attendance. In particular, I wish to especially express my admiration and appreciation to Dr. Bernard Wetchler who contributed greatly to my education on many historical events noted briefly at the beginning of this talk.

In 1999, when Professor Paul E.M. Jarrett authored a description of Dr. Nicoll's accomplishments [1], it marked the 100th anniversary of the year in which Dr. Nicoll initiated "modern" Day Surgery—the year, 1899.

Dr. Nicoll, a surgeon, published his landmark article on the surgery of infancy in 1909 [2]. In this he described a 10-year surgical experience at the outpatient clinic in the Glasgow Hospital for Sick Children in which 8988 patients were treated as outpatients after operation. Nearly one-half of the patients were children less than 3 years of age.

Dr. Nicoll performed 7392 of these operations himself. They included hare lips, cleft palates, hernias, and the like. Time precludes a more lengthy description of his amazing accomplishments and philosophy, especially his criticism of hospitalization and his insistence on getting the children back to their nursing mothers as soon as possible.

Again, due to time constraints, I will note briefly some of the other more recent milestones in the development of the field of ambulatory surgery.

In 1916, Ralph Waters opened The Down-Town Anesthesia Clinic in Sioux City, Iowa, a "free standing" center [3]. Later, among the recognized early hospital based ambulatory units were those developed in:

- 1959 - by Eric Webb and Horace B. Graves in Vancouver, BC [4];
- 1962 - by David Cohen and John Dillon, at The University of California, Los Angeles, California, USA [5];
- 1970 - by Marie Louise Levy and Charles S. Coakley, at The George Washington University Medical Center, Washington, DC, USA [6].

The first successful freestanding ambulatory facility was developed in:

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1970 - by John Ford and Wally Reed, in Phoenix, Arizona, USA [7].

In case you are wondering, my ticket was punched as a card carrying ambulatory anesthesiologist approximately 37 years ago, while working with Drs. Levy and Coakley.

What have we learned during and since that time? What are some of the issues, which have been resolved or are still outstanding? How valid are our supporting data? As seen through my eyes, a brief description and analysis follows. First, a look at what was and what is.

In 1966 with the opening of the outpatient surgical unit at George Washington, the goals and objectives were to:

- reduce the cost of medical care—commonly referred to as “COST CONTAINMENT”,
- increase the availability of hospital beds for those who needed them, and
- offer the same quality of care as an inpatient without its inconveniences and the potential hazards of cross infection.

In 1966, acceptable patients were primarily those classified as ASA status 1 or 2, and procedures were short with no invasion of the body cavity. Currently ASA status 3 or 4 patients may be acceptable while procedures are often lengthy and frequently include those involving invasion of body cavities.

In the past, the primary anesthetic route was by inhalation while currently there is an emphasis on using the primarily intravenous or regional anesthesia techniques. Recovery required the use of rigid discharge criteria. These included a minimum stay and the requirement for ingestion of oral fluids and voiding (in adults) before discharge. Currently, there may be no requirement for a minimum stay. As a matter of fact, some facilities have established ground rules by which the “phase one” recovery unit may be bypassed entirely.

While inpatient surgery was the rule early on, outpatient surgery has now become the vogue. The current buzzwords continue to be cost containment. Additional concepts include patient satisfaction and patient safety. After 30 plus years we have a large database, which has been accumulated largely through observation and experience. What is left to study? How good are our reports? What is their design and biases? How valid are the conclusions?

This is the basis of my talk today. I have not made an active attempt to duplicate the presentations, which follow and will be presented in more detail later in the Congress. I will attempt to present an overview and perspective of where we are and where we should go from here. The data, which I shall present, are from the U.S. and Canada. I was unsuccessful in obtaining the results of recent studies from abroad.

1. Practice parameters of the American Society of Anesthesiologists

First, let us look at the American Society of Anesthesiologists (ASA) process for developing and defining these parameters. “Practice parameter” is the global term used by ASA and includes Standards, Guidelines and Advisories.

“Standards” are rules or minimum requirements. They include, for example, the Standard for Basic Anesthetic Monitoring. Standards were developed by consensus and before the current formal, evidence-based process was instituted.

Particularly relevant to outpatient surgery are several “Guidelines”—defined as recommendations or guides and one “Advisory” or report. All were subject to the application on an evidence-based model. They include:

- Practice Guidelines for Preoperative Fasting, published in 1999;
- Practice Advisory for Preanesthesia Evaluation, in 2002; and
- Practice Guidelines for Postanesthetic Care, in 2002.

Inherent in the development of these parameters is an extensive literature review in which the methodology, results, and validity of the data are quantified. In addition, the data are analyzed for the relationship between an intervention and an adverse outcome. For example, in the Practice Guidelines for Preoperative Fasting, there is a recommendation for withholding clear liquids for a minimum of 2 h prior to the administration of the anesthetic while a light meal should be withheld for at least 6 h [8]. Although these recommendations are based on gastric emptying times and seem prudent, published evidence in humans is silent on the relationship between fasting times, gastric volume, or gastric acidity and the risk of emesis/reflux or pulmonary aspiration, the adverse events.

The recommendations in the Practice Advisory for Preanesthesia Evaluation [9] are based on even softer data; hence the use of the term “advisory” as opposed to “guideline”. In the past, most outpatients were required to make an additional visit to the facility prior to the day of surgery in order to obtain a detailed history, perform a physical examination, and obtain laboratory data. Currently, the Advisory recommends that the preoperative visit prior to the day of surgery be performed in patients with a high severity of disease and/or those undergoing procedures with high surgical invasiveness. Although this advice seems prudent and rational, it has never been field tested for validity and hard data to support the recommendation are lacking.

Likewise, the recent summary of recommendations for discharge in the Practice Guidelines for Postanesthetic Care [10] include:

- the requirement for urination prior to discharge is no longer a routine and is limited to selected patients,

- the ability to drink and retain clear liquids is no longer a requirement and is recommended only for selected patients, and
- a mandatory minimum stay should not be required.

The literature, however, is insufficient to evaluate the benefits of employing these new criteria. Although not the original intent, the recommendations are based mostly on the consensus of experts, as are all three ASA products noted above. This is not meant to be a criticism of the tireless, thorough, and expensive undertakings of the American Society of Anesthesiologists. The ASA has provided an authoritative set of recommendations, which have markedly improved patient satisfaction while presumably not increasing risk. Let us make it perfectly clear, however, that although outcome research is not supportive the benefits probably exceed the risks. In effect, then, the quality of care continues to be based primarily on:

- risk related to benefit,
- cost related to benefit,
- patient satisfaction, and
- physician comfort.

2. Outcome research

2.1. Association data

FASA: in 1984, nearly 20 years ago, Herb Natof participated in a study sponsored by the Federated Ambulatory Surgery Association (FASA) [11]. 87,492 outpatients were studied to determine the relationship between anesthetic technique and the incidence of complications. The highest incidence was found in patients whose surgery was performed using local and sedation. In 3000 of these patients, the sedation was administered by the surgeon. To this day, non-anesthesiologist administered sedation/analgesia remains a major source of morbidity and mortality. In addition, recent efforts by ASA have been directed at defining levels of sedation, the continuum, and the probability of adverse events as the depth is increased [12].

PIAA: The Physician Insurers Association of America (PIAA) represents 53 doctor owned insurance firms. It explores liability related to medical claims of their insured practitioners and some facilities. In the summer of 2002, their publication PIAA Research Notes was dedicated to the subject "Ambulatory Surgery Centers" [13]. Of note in the PIAA Data Sharing Project is that, since 1985, over all of their insured, there were 172,000 closed malpractice claims totaling \$9.2 billion in indemnity.

One thousand eight hundred and eighteen claims, or 1%, involved Ambulatory Surgery Centers. In terms of money spent, \$46 million was allocated for indemnity and \$20 million for defense expenses. The claims for ambulatory surgery are increasing in frequency but at a rate slower than other medical malpractice claims.

Of particular note is the experience in the field of Anesthesiology. In 1985–2001, the average indemnity for anesthesiologists per claim was \$167,180, the highest average indemnity of all physician specialties. Between 1997–2001, however, the average indemnity had decreased by two-thirds to \$48,357. Much of the improvement in anesthesia care has been attributed to the development and implementation of the American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring and the Practice Guidelines for the Management of the Difficult Airway. In the ASA's Closed Claims study, respiratory related claims have declined from 36% in the 1970s to 14% the 90s [14].

3. Outcome measures

Fried and Twersky have identified several measures for measuring outcomes for ambulatory surgery. These include: cancellations, admissions, morbidity and mortality, readmissions, resumption of activity and patient satisfaction [15]. Several of these parameters will be discussed.

3.1. Readmissions

In two studies of ambulatory surgery patients [16,17], the rate of return of the patient to the hospital, ambulatory surgery unit, or emergency room within 30 days ranged from 1.1 to 3.0%. Many readmissions were unrelated to complications of the surgical procedure or anesthetic care. In both studies, the primary predictor for readmission was genitourinary surgery. Once the patients had initially been discharged home after surgery, anesthesia-related symptoms did not cause readmission. As in much of the outcome studies on ambulatory patients, readmissions represent a low frequency event.

3.2. Admission and death in the elderly

As described in the previous section, readmissions were a low frequency event. In an effort to evaluate a large population, Fleisher et al. [18] focused their research interests on a Medicare administrative database. They studied admission and death within 7 days and 30 days after outpatient procedures in the elderly. Five percent of the claims for a 5-year period (1994–1999) were reviewed. Their review covered 564,267 procedures of which 360,780 had been performed in hospitals; 175,288 in ambulatory surgical centers; and 28,129 in an office setting.

The rate of the adverse events studied was lowest in the ambulatory surgical center and highest in the outpatient hospital units. The latter was expected; however, the fact that adverse events were more frequent in an office setting compared to

the ambulatory units was unanticipated. This subject will be discussed later.

The study of this large medicare administrative data set had its limitations. For example, during the 5 years studied, there were 156 deaths. Yet specific causes of neither mortality nor admission could be determined with certainty. They could have been influenced by anesthesia, surgery, patient disease or a combination as well as nonsurgical factors such as an automobile accident occurring post discharge. The authors concluded that the value of the study was to determine current practice patterns and to generate hypotheses for future studies.

3.3. Office-based surgery

The study of the medicare data base noted previously, is not the only one identifying the risk of procedures performed in an office setting. Vila et al. [19] compared surgical outcomes in offices and ambulatory surgery centers in the State of Florida. The data were obtained from the Florida Board of Medicine for Office Based Surgery and from the Florida Agency for Health Care Administration for Ambulatory Surgical Centers.

All adverse incident reports to the Florida Board of Medicine for procedures from April 1, 2000 to April 1, 2002 were reviewed. The number of office procedures performed during a 4-month period were used to estimate the total number of procedures; i.e. the denominator. Precise data were reviewed on procedures performed in the year 2000 in the ambulatory surgery centers since all were required to be reported.

Adverse events occurred at a rate of 66 and 5.3 per 100,000 procedures in offices and ambulatory surgery centers, respectively. The death rate per 100,000 procedures performed was 9.2 in offices and .78 in ambulatory surgery centers. There was an approximately 10-fold increased risk of adverse incidents and death in the office setting. These findings led to the establishment of many regulations to improve the safety of the patient in the office setting. They include a limitation in the duration of elective cosmetic and plastic surgeries as well stipulations when the presence of an anesthesiologist would be required. Experience in the State of Florida as well as other regions of the USA has led the American Medical Association and its partners to develop Office-based Surgery Core Principles for regulation of office-based surgery which can be adopted by States and other jurisdictions [20].

4. The future

By now, it should be obvious that we must require reporting of events from all centers performing ambulatory surgery. The precise identification of the risk of the patient's disease, anesthesia, and procedure can only be identified by prospectively collecting this information. Risk assessment is deter-

mined as follows:

$$\frac{\text{numerator}}{\text{denominator}} = \frac{\text{indicators or outcomes}}{\text{risk} - \text{adjustment}^*}$$

* age; American Society of Anesthesiologists physical status; surgical procedure; type of anesthetic administered, etc.

The goal is to identify "Benchmarking", or "Best practices", to ensure Quality Improvement, and to establish policies and procedures based on valid data. Conclusions based on information, which is incomplete, or limited to a local jurisdiction can be challenged. In addition, voluntary participation in the data collection process may fail to identify all adverse events. In other words, what is required is a national database with universal participation originated and directed by physicians or mandated and directed by government agencies, payers, and accreditation bodies.

The question is whether or not this is a pipe dream or is it being done at any level in the field of medicine. Believe it or not, a model was developed in 1994 by the largest single health care provider in the USA: The Veteran's Health Administration. Their system includes 123 VA medical centers, which perform major surgery.

They have implemented a National Surgical Quality Improvement Program known as NSQIP. It is the first nationally validated, outcome based, risk adjusted, and peer controlled program in major surgery. Preoperative and intraoperative data are collected prospectively. The data are used for benchmarking and quality improvement. In one of its more recent 30-day mortality study of 727,000 cases, mortality was reduced by 27% and mortality by 45% [21].

Why has this model not been duplicated by others? Why is it not in place in facilities in addition to the VA? It is costly and requires a tremendous effort to collect, input, and analyze the data. The U.S. Congress requires that outcomes in VA hospitals be reported and funds it accordingly. Currently, specialty organizations such as the American College of Surgeons have entered into a joint study with the VA to collect data from 14 non-VA hospitals. The study is funded by the U.S. Federal Agency for Health Care Research and Quality under a research grant.

Perhaps this could represent a method and model which the Society for Ambulatory Anesthesia and the Federated Ambulatory Surgery Association should pursue. One way or another we must collect large samples of meaningful data.

Thank you again for the opportunity to address the 5th International Congress on Ambulatory Surgery. It is has been a great privilege to attempt to follow in the footsteps of Dr. Nicoll.

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